Message Text

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PAGE 01 STATE 206857

15
ORIGIN HEW-08

INFO OCT-01 EUR-25 ISO-00 SCI-06 RSC-01 /041 R

66617
DRAFTED BY: DHEW/FDA/JRWEINROTH,MD/SAM D. FINE
APPROVED BY: SCI/SA:MSBEAUBIEN
DHEW/OIH/MACODDING
EUR/NE:SPDAWKINS
---------- 084020
R 192134Z SEP 74
FM SECSTATE WASHDC
TO AMEMBASSY COPENHAGEN

UNCLAS STATE 206857

E.O. 11652: N/A
TAGS: ECON, TBIO, DA
SUBJECT: COMMERCIAL PROGRAM: FDA - REQUEST FOR RELEASE OF
FDA CONTROLLED DRUG

REF: COPENHAGEN 2449

1. RESPONSIVE TO REQUEST OF NATIONAL HEALTH SERVICE, DENMARK, THROUGH U.S. DEPARTMENT OF STATE CHANNELS, FDA AUTHORIZES THE SHIPMENT BY WYETH LABORATORIES, PHILADELPHIA, PENNSYLVANIA, OF 100 GRAMS OF SOMATOSTATIN PARENTERAL TO DR. K. LUNDEBACK, 2 MEDICINSKE UNIVERSITETSKLINIK, KOMMUNEHOSPITALET, AARHUS UNIVERSITY, AARHUS, DENMARK FOR CLINICAL EVALUATION.

2. COPY OF LETTER FROM FDA TO WYETH LABORATORES BEING AIR MEILD TO EMBASSY.

3. FUTURE INQUIRIES OF THIS NATURE SHOULD BE ROUTED TO OFFICE OF INTERNATIONAL AFFAIRS, FDA. TEXT OF APPRORIATE SECTION, FD&C ACT, AS FOLLOWS:

"CONDITIONS FOR EXEMPTION OF NEW DRUGS FOR INVESTIGATIONAL USE.... THAT WHERE A NEW DRUG LIMITED TO INVESTIGATIONAL USE IS PROPOSED FOR SHIPMENT TO A FOREIGN COUNTRY FOR
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CLINICAL INVESTIGATION, IN LIEU OF THE FILING OF A 'NOTICE OF

CLAIMED INVESTIGATIONAL EXEMPTION FOR A NEW DRUG' (FORM FD 1571), THE COMMISSIONER WILL AUTHORIZE THE SHIPMENT OF THE DRUG IF HE RECEIVES, THROUGH THE DEPARTMENT OF STATE, A FORMAL REQUEST TO ALLOW SUCH SHIPMENT FROM THE GOVERNMENT OF THE COUNTRY TO WHICH THE DRUG IS PROPOSED TO BE SHIPPED. THIS REQUEST SHALL SPECIFY THAT SAID GOVERNMENT HAS ADEQUATE INFORMATION ABOUT THE DRUG AND THE PROPOSED INVESTIGATIONAL USE, AND IS SATISFIED THAT THE DRUG MAY LEGALLY BE USED BY THE INTENDED CONSIGNEE IN THAT COUNTRY. THIS PROVISION IS APPLICABLE ONLY WHERE THE DRUG IS TO BE USED FOR THE PURPOSES OF CLINICAL INVESTIGATION AND DOES NOT APPLY WHERE IT IS INTENDED FOR COMMERCIAL MARKETING OR USE IN ROUTINE MEDICAL PRACTICE." KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, FOOD & DRUG REGULATIONS, MEDICAL RESEARCH
Control Number: n/a
Copy: SINGLE
Draft Date: 19 SEP 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974STATE206857
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH,MD/SAM D. FINE
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D740264-0443
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t19740930/aaaaazms.tel
Line Count: 74
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: COPENHAGEN 2449
Review Action: RELEASED, APPROVED
Review Authority: martinjw
Review Comment: n/a
Review Content Flags:
Review Date: 09 MAY 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <09 MAY 2002 by maustmc>; APPROVED <31 JAN 2003 by martinjw>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: COMMERCIAL PROGRAM: FDA - REQUEST FOR RELEASE OF FDA CONTROLLED DRUG
TAGS: ECON, TBIO, DA, FDA
To: COPENHAGEN
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005

Declassified/Released US Department of State EO Systematic Review 30 JUN 2005